MICRO
BEEF TECHNOLOGIES

MAKING BEEF BETTER

July 5, 2005

Mr. Neil Hammerschmidt
Regulatory Analysis and Development, PPD, APHIS
Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Docket No. 05-015-1 Comments to the NAIS "Draft Program Standards"

Dear Neil,

Please find attached Micro Beef Technologies response to the NAIS "Draft Program Standards and request for comments.

We appreciate the opportunity to present our recommendations and it is our hope that USDA finds these comments useful. We believe that these recommendations, including a private sector central database, an integrated service provider infrastructure and modified numbering system enhance the efficiency and effectiveness of the NAIS and are fundamental to the ongoing development and implementation of a sustainable NAIS.

Sincerely,

Mark J. Shaw
CEO

RECEIVED

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United States Department of Agriculture

Animal Plant and Health Inspection Service
NAIS "Draft Program Standards"
Docket No. 05-015-1

July 5, 2005

Comments submitted on behalf of Micro Beef Technologies, Ltd.

Micro Beef Technologies appreciates the opportunity to comment on the NAIS "Draft Program Standards" and to offer these recommendations to USDA in hopes of furthering a successful NAIS System implementation which meets the objectives of both federal and state health authorities as well the interests of animal producers.

After careful review of the discussion document published by USDA April 25, 2005 we believe that there are many criteria outlined by USDA that we agree with however, there also exists levels of complexity and red tape that we believe can be streamlined for a more successful systems implementation without compromising disease management. Following is an outline of those areas we believe need to be addressed for a successful NAIS.

Background

Micro Beef Technologies (Micro Beef) has more than 19 years experience identifying, tracing and tracking millions of individual animal's location, health and performance information and over 35 years experience as a manufacturer of computerized management systems for the beef industry. Micro Beef has gained extensive experience in the field of individual animal identification and management by pioneering patented systems that are virtually identical to the proposed NAIS. Through these many years of experience Micro Beef has developed a deep understanding of the inherent complexities and requirements necessary to effectively track, trace and manage individual animals without impeding the normal commerce of animals.

NAIS – A Private Sector Central Database and Infrastructure

Micro Beef recognizes the immediate need for a NAIS but strongly supports its implementation as a private sector System. Producers of all species and their respective trade organizations have clearly stated their desire to implement a private sector solution along with service providers, key state health officials and members of Congress. To date USDA fails to recognize that the NAIS is best suited as a private sector implementation.

The following criteria we believe supports of the need for a private sector supplied NAIS.

- Small Incidence – While the impact of diseases along the lines of BSE, FMD etc are catastrophic to animal agriculture, USDA has reported that only ½ of 1 % of all animals from the national herd are involved in disease traceback surveillance, monitoring and eradication activities annually. If it were impossible for the private sector to provide a System that met the needs of both industry and health officials then it would be well understood that government should fill the need. However, through an Industry-Government partnership, the need can be fulfilled and effectively meet the needs of all involved.

- Funding - USDA does not have adequate funding to pay for the costs of implementing or operating a System that tracks the national herd. Given that the costs associated with the NAIS implementation will be borne by the private sector, and that the private sector has developed the proprietary and patented systems required to accomplish the implementation, the private sector is best suited to establish a System that meets commercial and health management requirements. It is well understood throughout our

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Nations history that the private sector is more efficient and effective in providing consumers systems and products.

- Confidentiality - In an attempt to preserve producer confidentiality interests USDA has proposed legislation that would protect the confidentiality of federally collected ID information. This is a necessary and very complex topic and yet there is no guarantee that private information will be protected from FOIA requests even with this and other legislation. Industry has argued that there is no need for USDA and potentially numerous other departments to have the national herd information in a public central database. In contrast a private central database will contain the healthy national herd, approximately 99.5% of the animals, and in the private sector system producer premise and animal information will be protected from FOIA requests as well as data mining.

- Intellectual Property – USDA has promoted in the Draft Program Standards that they will make available to industry stakeholders a Standardized Animal Identification and Tracking System in addition to a National Animal Repository. Given the fact that private enterprises like Micro Beef have invested millions of dollars in the development of Systems that accomplish these functions and that Micro Beef has extensive intellectual property in the fields of animal tracing and health management it appears highly inappropriate for government to seize and utilize these systems without a license from the owners of the intellectual property. Furthermore, it also seems inappropriate for government to reinvent and develop systems that compete with private sector animal tracking solutions.

The private sector is currently capable of supplying the System and the necessary oversight and has committed to work collaboratively with USDA. As a result we believe there is little reason for USDA to reinvent the capabilities currently available in the private sector to database the entire national herd as long as health officials including state and federal authorities have complete and immediate, unfettered access to a private central national database that supplies health officials the necessary animal and premise tracing information.

The commonly accepted industry model that outlines the function of a private sector solution working in conjunction with health officials is depicted in the chart below.

NAIS Model and Data Flow
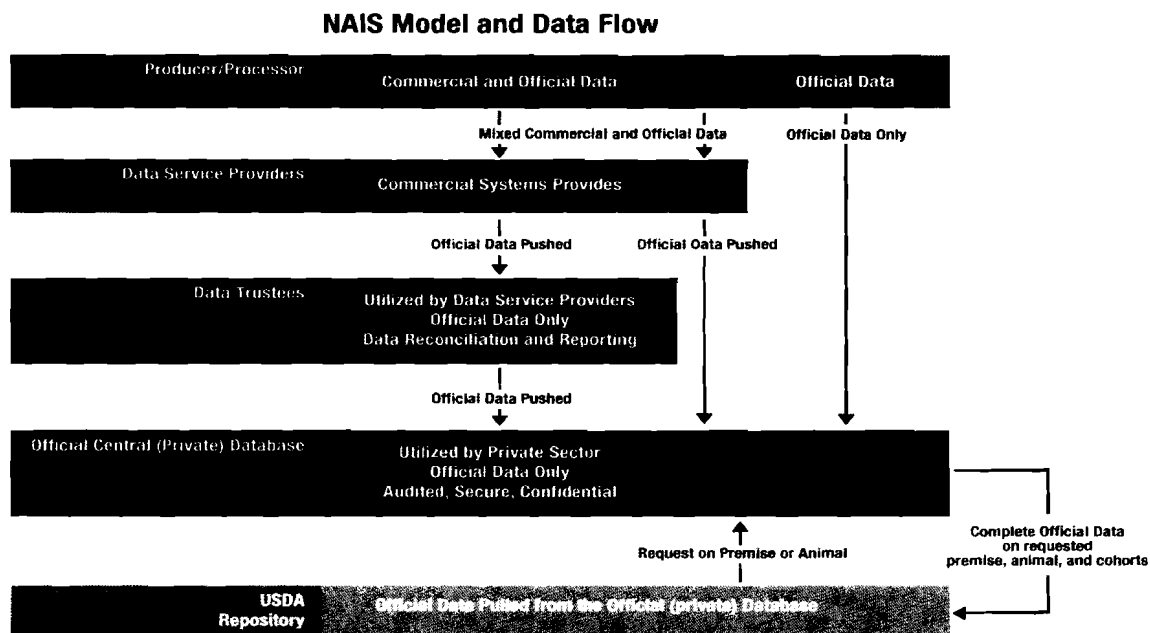
A private sector NAIS Model and implementation will provide the following benefits:

1. Protects producer confidentiality and privacy interests,
2. Lowers the costs of implementation and operation of the NAIS,
3. Increases the speed of implementation,
4. Enhances the efficiency of the systems operation,
5. Minimizes barriers to entry thus maximizing producer participation,
6. Minimizes the impact of the NAIS on normal animal commerce,
7. Provides reconciliation and verification information to producer participants to ensure data and systems integrity,
8. Implements animal numbering systems and devices that meet the needs of producers and that are readily available,
9. Respects intellectual property rights,
10. Utilizes existing Industry assets to provide an implementation that does not unduly increase the size of government.

Micro Beef is uniquely qualified to provide a private sector NAIS based upon our extensive intellectual property, experience and expertise.

Micro Beef was the first industry based NAIS demonstrated to USDA that;

1) Envisioned, communicated and demonstrated a working technology neutral infrastructure linked with a private central database enabling participation of multiple species and data service providers,

2) Has the ability to extend the necessary NAIS intellectual property to the industry,

3) Offered real time confidential reporting to assure buyers and sellers that animals enrolled in the System had the required records,

4) Does not impede the normal movement and commerce of animals,

5) Can be implemented now

Numbering Systems

Essential to achieving the NAIS goal of 48-hour traceback is the implementation of an efficient and effective numbering system. We support the fact the USDA promotes a flexible and technology neutral animal identification system founded on identification standards driven by species specific criteria. We agree with USDA that the plan must be dynamic and that it must be designed from the outset to incorporate new and proven technologies as they become available.

The following considerations serve as foundational pieces that in Micro Beef's experience of dealing with millions of animals must be taken into account when evaluating numbering system requirements.

Numbering systems and the respective identification devices utilized for an effective NAIS must;

- Enable 48-hour traceback capability
- Be simple, flexible and easily implemented
- Be technology neutral but utilize national data and identification standards
- Be readily available to all industry stakeholders
- Not impede the normal movement and commerce of animals

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- Not negatively impact or significantly deviate from the normal means of identifying animals

- Not be burdensome to industry stakeholders responsible for implementing NAIS

- Not unduly increase the size of government

  Be cost effective

Micro Beef would like to offer what we believe is a simpler, more straight forward and time tested solution of identifying and tracing animals which can be applied to all animal species for use in the NAIS while effectively meeting the stated NAIS criteria.

Official AIN Tag bearing the US Shield

Micro Beef proposes that USDA remove the requirement of the Official AIN Tag as the sole and primary physical identifier for animals in the NAIS.

USDA calls for an official Animal Identification Number to be the same number that is encoded on an RFID bearing the US shield and attached to the animal. The known problem with this alternative is that no physical device placed on an animal is permanent. Tags of all type are lost, damaged, malfunction or become unreadable. This well established fact argues against requiring an initial, single, government based official identifier to be physically attached to the animal for its entire life. Moreover, in certain species, the unique animal identification device selected may not even be visible to an animal custodian or health official. Because a key consideration for the NAIS is to achieve standardization, and especially so when considering database management requirements of variable types of animal identification devices across species, common sense tells us that their must be a more effective and flexible means to accomplish system standardization to each species groups and their producers without compromising traceback integrity. To base an entire systems approach on an official tag given the differing needs of each species combined with the advancements of new identification technologies compromises the long-term viability of the system from the outset. The industry also has concerns about USDA being in the business of controlling the distribution and reporting of tags under a voluntary program where producers bear the full cost of the identifying the healthy herd, estimated to be roughly 99.5% of the national herd.

Universal Animal Identification Number (UAIN)

A much simpler approach is to utilize a unique, permanent database identification number for each animal to which all other identification methods are linked.

Micro Beef proposes that this database identification number be the same number as proposed by USDA, a government-issued 15 digit AIN or 840 number. The 840 number would be classified as a Universal Animal Identification Number or UAIN and would be a permanent and unique database number for a single animal that is linked with all physical device identifiers associated with the animal including an RFID, visual tag, retinal scan, DNA, brands and unlimited alternate identifiers. The use of a unique database identifier, or UAIN, is a standard practice for all major database service providers today. By utilizing the UAIN, USDA or a NAIS consortium administers the Official AIN and enables the near and long term systems flexibility of being able to incorporate those identification methods most appropriate or preferred by each species or producer. This is important when one considers the near-term transition period requirements and potentially more cost effective new identification technologies. Specifically the UAIN alternative also means that both currently accepted and new identification technologies may be easily adopted without having to re-engineer the Official Database over time. Micro Beef recognizes that some producers or programs may choose to encode the UAIN onto the RFID physical identifier which could be a user option but not required of all producers. In order to enable the normal commerce of animal identification, reporting and movement this alternative allows producers the ability to link a unique ISO- compliant RFID and other management identifications thereby providing animal producers flexibility, practicality and workable adoptable options.

By establishing a unique, permanent database number for the animal, the UAIN also allows easy re-tagging or re-identification. Under these proposed recommendations, retagging links a new physical identifier to the original UAIN. There would only be one UAIN, the original UAIN (or AIN), linked with one animal. Lookup is also improved with the proposed recommendation. When the producer replaces any identification device on the animal the UAIN database record for that animal is unchanged and it is linked to the new identifier and the old one retired, thus the system is less complex. Also, anytime a unique physical device number is entered into the computer to review a record, the unchanged UAIN is reported because it is linked directly to the current device number on the animal.

The Numbering System for individual animals recommended by Micro Beef provides for:

1. Permanent use of a unique permanent database Universal Animal Identification Number (UAIN) to which all ID devices and methods are permanently linked in the database.

2. Permanent allowed use of existing ID devices and methods linked to the database UAIN.

3. Permanent requirement for an Official Device Animal Identification Number (DAIN), to be linked to the database UAIN.

4. Transitional requirement of either an official RFID (DAINRF) or official Visual device (DAINVI) to be linked to the UAIN.

5. Post-transitional requirement for only the DAINRF to be used with optional DAINVI.

6. Permanent use of any ISO-Compliant RFID tag allowed as a DAINRF

7. Permanent use of existing visual device number systems on the DAINVI tag which contains an Official ID number

A. Database Numbers	Classification	Official/Allocated
1.Premise Number in Database	Unique/Permanent	Yes
2.Non Producer Participant Number in Database	Unique/Permanent	Yes
3.Individual Animal Number In Database UAIN	Unique/Permanent	Yes
B. Physical Device or Method (one or more linked to UAIN)		
1.Official DAINRF Any ISO	Unique	Yes
2.Official DAINVI	Unique	Yes
3.Alternate Visual Device	May be Unique	No
4.Alternate Retinal Scan	Unique	No
5.Alternate DNA Profile	Unique	No
6.Alternate Brand/Markings	State Unique	State
7.Alternate Other	May be Unique	No
C. Group / Lot ID	Unique	Yes

UAIN Management – Permanent Database Identifiers vs. Permanent Physical Animal Identifiers

Under Micro Beef's proposed recommendations USDA would allocate the UAIN number to AIN Managers, defined as Data Service Providers, Data Trustees and others who provide data collection and reporting services to producers. Prior to tagging, a producer purchases readily available RFID devices from the producer's normal supplier with no requirement to report the identification devices at the time of purchase.

When the producer is ready to attach identification devices he can then record the identifiers to each animal. At the time the producer reports NAIS event information a Data Service Provider or Data Trustee links the UAIN in the database to the identification devices and methods reported by the producer. Micro Beef recommends that the NAIS requirements allow for an infinite number of

alternate ID's to be recorded and reported for the animal to provide flexibility, redundancy and integrity to the system.

Animal identification integrity is improved because the database identifier is tamperproof, permanent, cannot be lost and as previously discussed provides the needed flexibility to accommodate new and proven technologies. An expectation that any type of physical identifier placed on the animal provides permanency or integrity is flawed when one considers that any tag may be lost, damaged, unreadable, removed or tampered with. Thus, logic supports that an animal health traceback investigation becomes a database issue not an official tag issue.

There is no known advantage for using an Official Tag to know health condition or the true identity of the animal and its cohorts. An Official Tag attached to the animal will provide an investigator no more information than a standard unique ISO device when physically inspecting animals. Therefore, in an animal health investigation a health official would determine all of the identifiers associated to the animal (Premise ID, ISO RFID, visual ID's, back tag, retinal scan, DNA string, brands, markings, etc) and enter that information into a query of the Official Private Central Database to acquire the appropriate traceback information.

Prohibitions on Tampering with or Removing Official Identification Devices

One could argue that the benefit of an Official Tag is that state and federal government can promulgate laws that prohibit the removal of official tags, thus preventing tags being tampered with adding integrity to the System. Current Industry practices in many production segments mean removing previous identification devices and replacing them with devices that reflect the management practices of a given location. The identifiers intended to be removed can be recorded in various database systems including the central private database for linking purposes. It will be a mistake to pass laws that make it illegal to replace RFID devices. Producers should have the flexibility to remove and reattach RFID's with the requirement that these replaces RFID must be reported. With respect to any type of removable identifiers we have to recognize that if one is motivated to intentionally tamper with an animal's identification tag to purposely avoid a traceback responsibility neither physical animal identification device nor law will keep that person from removing the ID. What we must focus on is a System that requires the reporting of event information to the database as opposed to a fixation on an Official ID tag.

NAIS – A System Designed to Enable Animal Tracing not Tag Tracking

Management of the UAIN process as described above would be simplified because physical ID devices would not need to be allocated, tracked or managed by AIN manufacturers, distributors or producers. The idea of Official Tags bearing USDA allocated number and the US shield tracked from manufacturer to distributor to dealer to producer creates an additional tracking system for tags supplemental to an animal traceback system. The assumption is to create a bookend system that at minimum tracks a tag sold to an initial premise allowing an investigation to be conducted between the initial premise and any potential intermediate premises where the suspect animal could have been located. The fact is that an investigator can perform that same function in the database with premise information, the UAIN and animal identification information.

The notion of tracking tags only serves to complicate the implementation and ongoing operation of the NAIS by creating an excessive number of new, costly and unneeded databases which only add additional layers of complexity and bureaucracy to the NAIS.

In simple terms, the contemplated tracking of Official Tags as stated above means that 5 separate tag tracking databases would be required to follow a single 840 number from USDA to the producer who buys an Official Tag.

In contrast by using the recommended UAIN example only 2 databases would be involved, one at USDA which generates and records the UAIN (database identifier) and to which Data Service Provider it was allocated and another which represents the premise to which the UAIN was

assigned. The premise would then report the physical animal identifiers involved in an official NAIS event.

Tag Tracking Impedes Normal Commerce

These additional tag inventory systems would put an un-needed and undue burden on the industry that will impede normal commerce. Let's look at another example which describes the new requirements that a tag supplier like a dealer store, veterinarian or distributor would need to meet in order to sell the Official Tag.

Let's assume for beef that the average herd size is 35 head and that the producer's supplier purchases Official Tags in 50 unit packages from the manufacturers. Let's also assume that greater than 80% of these 50 unit packages will have to broken by the supplier in order to fill the needs of these small herds. This means that tag suppliers will have to individually read each tag, make a record of each tag, print a list of each tag sold to each producer, affix the list of the Official Tags to the new package for the producer and finally report it to USDA. Fundamentally, this is predictably an unworkable and unnecessary system.

As demonstrated in the Canadian System a high percentage of Official Tags being tracked utilizing a similar method are always unaccounted for as to their location at any given time as they are lost in a transitional float between manufacturers, distributors, dealers, and producers. Add to that that tags stored at a producer premise can be lost or stolen and one can easily anticipate that producers and suppliers will object to being held responsible for Official Tags when the sole responsibility being asked of them in the implementation of the NAIS is to report premise and animal identification information for health management purposes of the animals being moved in commerce.

By utilizing the UAIN combined with a non-official but unique identification like an ISO RFID tag, animal producers and the industry have a system that is easily and successfully implemented and that preserves individual animal integrity without compromising the 48 hour traceback requirement or impeding commerce.

Simplification of the Individual Animal Numbering System and Allocation Methods

Micro Beef recommends that the Numbering Systems be modified to reflect comments made by Micro Beef and outlined in Figure 1 of this document and as supported by the previous comments made by the Beef Information Exchange to USAIP. This described method of identifying animals for tracing purposes is successfully used today in commercial applications and therefore the only new step in the process for a producer participating in the NAIS is the requirement to report the movement of animals to an official database.

Figure 1. Recommended Allocation and Distribution of Animal Identification
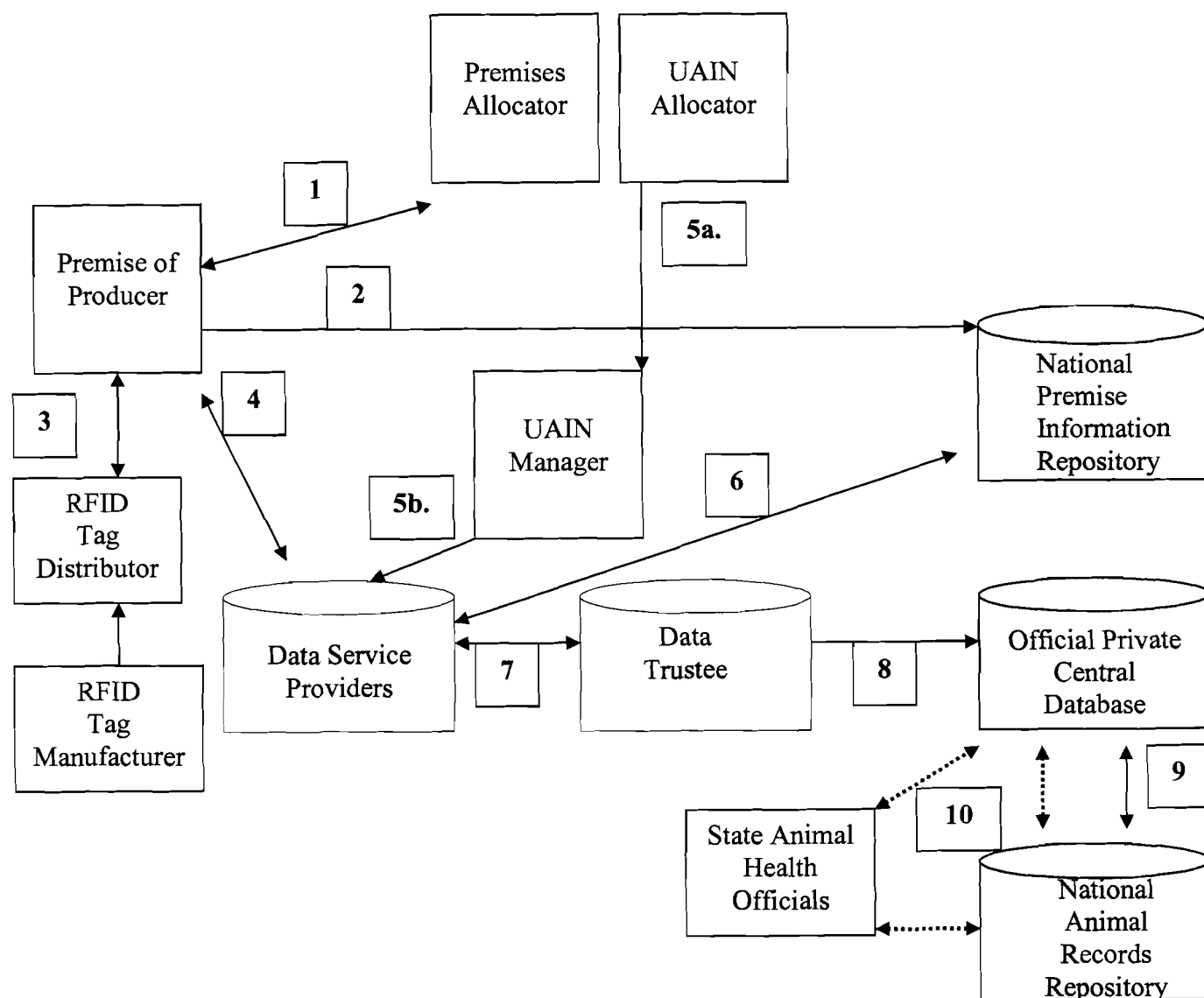
1. Producer requests Premise Number from Premise Allocator

2. Premises information stored in National Premise Information Repository

3. a. A producer sources RFID tags encoded with a unique identification number that conforms to ISO standards from their distribution channel of choice, no restrictions and readily available tags.

   b. A tag distributor sources tags from a tag manufacturer neither which has any official reporting requirement to USDA.

4. A producer selects a Data Service Provider/Trustee and reports the RFID numbers applied to animals.

5. a. UAIN Manager/Data Service Provider receives the 15 digit 840 number UAIN from the USDA UAIN Allocator.

b. The Data Service Provider links the Universal Animal Identification Number to the RFID and all other identifiers reported for the animal by the producer.

6. The Data Service Provide confirms/verifies premise information

7. The Data Service Provider pushes official data to a Data Trustee. The Data Trustee is certified and audited by USDA.

8. The Data Trustee pushes official data reported for the premise to the Official Private Central Database.

9. The Official Private Central Database sends to the USDA NARR the UAIN numbers that have been reported. From the Official Private Central Database the Data Service Provider/Producer receives commerce based confirmation reports to verify reported events. The USDA NARR has a mirrored copy of the data structures used in the Official Central Private Database but does not have the complete data on the animals in the healthy herd unless step 10 occurs.

10. As animal health investigations occur, USDA and state health officials access the secure Official Private Central Database and pull the official information specific to a premise or target animal and its cohorts. State Veterinarians would have equivalent status as USDA for accessing the official data and may pull data from either the Official Private Central Database or Federal NARR.

Recommended NAIS Clarifications and Definition Enhancements

- **Animal Identification Numbers** (AIN) – A numbering system for official identification of individual animals in the United States which are allocated by APHIS containing 15 digits with the first 3 being the country code (840 for the United States). The purpose of the AIN is to establish a permanent tamperproof database identification number for individual animals. Micro Beef recommends that the AIN be renamed the **Universal Animal Identification Number** or **UAIN.**

  o Animal Identification Numbers – The (UAIN) may be used at the producer's option as the RFID number or as an alternative, another ISO compliant number maybe used.

- **AIN Managers** – Micro Beef recommends that AIN Managers be defined to represent companies that receive allocations of UAIN's from USDA which in turn will be utilized as permanent database identification for the animal. Under this recommendation AIN Managers would be Data Service Providers, Data Trustees or others who participate in linking an ISO RFID device on the animal and subsequent alternate ID's to the UAIN in a database.

- **AIN Tags** – Micro Beef recommends that AIN Tags be reclassified as **Device Animal Identification Number-Radio Frequency Identification or DAIN – RF** tags. A DAIN-RF would be required to be attached to each animal or sub-dermally implanted in each animal as determined by each species group and meets ISO standards so that each ID is unique. The DAIN-RF Tag will be considered neither official nor bear the US Shield. DAIN-RF tags would continue to be required to display the encoded ISO number on the outside of the tag. By requiring that each manufacturer of RFID tags adheres to ISO standards USDA and the industry is assured that RFID's are unique. By utilizing ISO RFID tags for NAIS identification, manufacturers are not required to change their normal manufacturing processes or required to establish a unique color for official identification. DAIN-RF tags used for beef production should not be limited to a one-time use. Re-useable tags have been used to uniquely identify animals in the beef industry for over 10 plus years and have been successfully used to uniquely identify an animal when linked with a UAIN. The use of re-useable tags reduces the costs of identifying the animal significantly, the savings which effectively pays for cost of the NAIS database and a portion of the systems cost of

the producer while providing flexibility with integrity to the system. The allowance of re-useable RFID tags should be a permanent NAIS capability.

- Under this recommendation **RFID Tag manufacturer** can replace the term **AIN Tag manufacturer**. Thus a RFID manufacturer would be one that USDA verifies is certified as ISO compliant.

- **AIN Tag Distributors** - Under this recommendation the definition for AIN Distributors can be removed as the distribution of animal identification devices to include RFID would occur through normal commercial means.

- **Electronic Identification**

  o Micro Beef supports that USDA should have the standards setting responsibility for electronic identification but also encourages USDA to not be in the device selection business for the following reasons.

    - Stifles innovative improvements of ID technology

    - Innovation benefits include improved quality and reduced costs to stakeholder participants

- **Group/Lot Identification Number (GIN)** – Micro Beef recommends that the rule be amended to state that each animal reported in a group movement be required to have an individual animal group ID tag attached to each animal in the group and that when reported to the Official Database the number of head being moved in each group should be required in the movement report. Otherwise one has no way to prove they were part of the group once they are intentionally or accidentally commingled at a premise location.

- **Officially Identified** - Based on the recommendation that the UAIN database identifier is adopted as the Official Identification Micro Beef suggests that term Officially Ear tagged be replaced and that a new definition for OFFICIALLY IDENTIFED be established in its place. Officially Identified means; An animal that is uniquely and officially identified with a tamperproof database identifier allocated to Data Service Providers or Data Trustees by USDA and known as a Universal Animal Identification Number (UAIN). An Officially Identified animal is one that has been reported to the Official Private Central Database for purposes of NAIS tracing. The UAIN will be linked to the physical identifiers associated to an animal.

- **Definitions that need further clarification:**

  - Commingling is not well defined for beef – the Code of Federal Regulations provides specific definitions for commingling swine and sheep but not a clear definition for beef. Arguably this is probably the single most important issue affecting disease traceback. Micro Beef suggests that a definition for commingling must mean that an animal was not prohibited from coming in contact with another animal.

  - The definition for a unit of animals is variable among species and without further definition could be considered ambiguous in establishing group identification.

  - Production systems can be interpreted to have variable meanings within and across species.

Summary

Micro Beef believes that the recommendations as outlined are of critical importance and merit serious consideration by USDA in the development of the NAIS. We believe that these proposed recommendations will improve the acceptability of the NAIS implementation without compromising the 48-traceback objectives and do so without impeding the normal commerce and movement of animals. These proposed recommendations will also reduce the overall costs of implementation. We hope that these comments are found to be useful and constructive and we look forward to continuing to work with USDA and the industry in making a successful NAIS implementation.